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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,425

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Soo-Kyung Kim

P31590 USA

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FOX ROTHSCHILD LLP
2000 MARKET STREET
10th Floor
PHILADELPHIA, PA 19103

EXAMINER

FORMAN, BETTY J

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,425	Applicant(s) KIM ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Interpretation

1. The claims are drawn to a biochip readout device. The claims include numerous recitations of intended use for the device and various elements of the device. The courts have stated that recitations of intended use do not differentiate a claimed device from the prior art.

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

The courts have also stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

The claims are given the broadest reasonable interpretation consistent with the intended use claim language and specification wherein the use does not define and/or limit the structure of the device.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 10, 12, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 1, Wang teaches a biochip readout device comprising a rotatable biochip cartridge (#74) having a biochip installed on the disc (e.g. segment #70, Fig. 5, Column 14, lines 35-44). Wang further teaches a light reception means for receiving beam from the disc (i.e. focusing, tracking & header detector #134/136) having a light source scanning the disc (#102, Column 11, lines 40-67), a focusing/tracking control using the light reception means (Column 15, lines 28-45), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 15, lines 32-36), an optical pick-up device for analyzing the biosignal from the biochip (#124, Column 15, lines 45-58, Fig. 7) and a system and output controlling unit for monitoring analysis information, processing the signal (Column 17, lines 13-55).

Regarding Claim 4, Wang teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit using a single light source while controlling focusing and tracking i.e. single light source with 3 different paths (Column 15, lines 10-53).

Regarding Claim 10, Wang teaches the device wherein the disc is formed by spotting biocells within a groove (i.e. beads having biomolecules, Columns 13-14).

Regarding Claim 12, Wang teaches the device comprising a patterning device (printer) comprising a servo device for rotating the disc (raster scanner) and a printer for patterning the biocell on the substrate and a controller (servooptics) for controlling the entire system for rotation and printing (Column 12, lines 33-43 and Column 17, lines 24-47).

Regarding Claim 15, Wang teaches the device further comprising a communication device for transmitting data and signals via predetermined connection to a readout device (i.e. display, Column 17, lines 13-23).

4. Claims 1, 3, 4, 8, 10, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Krutzik (U.S. Patent No. 7,141,416, filed 12 July 2002).

Regarding Claim 1, Krutzik teaches a biochip readout device comprising a rotatable biochip cartridge (#110) having a biochip installed on the disc (e.g. microarray #147, Fig. 15, Column 13, lines 3-20). Krutzik further teaches a light reception means for receiving beam from the disc (i.e. focusing and tracking via bottom detector #157) having a light source scanning the disc (#150), a focusing/tracking control using the light reception means (Column 13, lines 21-52), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 14, lines 21-44 and Column 15, lines 57-64), an optical pick-up device for analyzing the biosignals from the biochip (top detector #158, Column 12, lines 21-52, Fig. 16) and a system and output controlling unit

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for monitoring analysis information, processing the signal (#166/168, Column 13, lines 46-52).

Regarding Claim 3, Krutzik teaches the device further comprising an optical recording unit (analyzer #168) for recording signals in response to trigger mechanism (#126/160) and output unit for producing analysis information (Column 3, lines 25-67).

Regarding Claim 4, Krutzik teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit (via trigger mechanism) using a single light source while controlling focusing and tracking (Column 13, lines 21-52 and Column s 14-15).

Regarding Claim 8, Krutzik teaches the device wherein the biodisc is attached to the cartridge using an adhesive (#118, Column 7, lines 21-24).

Regarding Claim 10, Krutzik teaches the device wherein the disc is formed by spotting biocells within a groove (Column 19, lines 12-31 and Column 25, lines 42-47).

Regarding Claim 11, Krutzik teaches the device wherein the reflective film is selectively reflect allowing some light to pass and some light to be reflected (Column 15, lines 22-29, Fig. 20).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11, 15-21 and 25 are rejected under 35 U.S.C. 103(a) as obvious over Krutzik (U.S. Patent No. 7,141,416, filed 12 July 2002) in view of Sandstrom (U.S. Patent No. 6,545,758, issued 8 April 2003).

Regarding Claims 1 and 2, Krutzik teaches a biochip readout device comprising a rotatable biochip cartridge (#110) having a biochip installed on the disc (e.g. microarray #147, Fig. 15, Column 13, lines 3-20). Krutzik further teaches a light reception means for receiving beam from the disc (i.e. focusing and tracking via bottom detector #157) having a light source scanning the disc (#150), a focusing/tracking control using the light reception means (Column 13, lines 21-52), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 14, lines 21-44 and Column 15, lines 57-64), an optical pick-up device for analyzing the biosignals from the biochip (top detector #158, Column 12, lines 21-52, Fig. 16). Krutzik teaches the device comprises a system and output controlling unit for monitoring analysis information, processing the signal (#166/168, Column 13, lines 46-52). Krutzik further teaches the device compares signals to known and/or reference analytes (Column 17, lines 8-12 and 37-41) and further that the device provides for automated analysis of physiological disorders (Column 1, lines 66-Column 2, line 8). All of this clearly suggests the device is a diagnostic device for monitoring and comparing database information.

Furthermore, computerized diagnostics was well known and routinely practiced in the art at the time the invention was made as taught by Sandstrom (Column 4, line 53-Column 5, line 34). Sandstrom teaches a device wherein all elements of biochip

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construction, use and analysis are provided within the computerized system whereby the information is efficiently processed, stored and/or interpreted (Column 5, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diagnostic analysis of Sandstrom to the device of Krutzik. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the well known benefit of efficient processing and interpreting as taught by Sandstrom (Column 5, lines 61-67).

Regarding Claim 3, Krutzik teaches the device further comprising an optical recording unit (analyzer #168) for recording signals in response to trigger mechanism (#126/160) and output unit for producing analysis information (Column 3, lines 25-67).

Regarding Claim 4, Krutzik teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit (via trigger mechanism) using a single light source while controlling focusing and tracking (Column 13, lines 21-52 and Column s 14-15).

Regarding Claim 5, Krutzik teaches the device wherein the trigger mechanism prompts the system to data collection when the trigger marking are detected thereby selecting for readout vs general scanning (Column 13, lines 35-52).

Regarding Claim 6, Krutzik teaches the device wherein a fluorescent signal is detected (Column 2, lines 60-63) and compared to known reference or concentration (Column 17, lines 9-12 and 37-41) and further teaches the device monitors and processes information (Column 3, line 25-Column 4, line 12) thereby teaches the structural elements required by the claim.

Regarding Claim 7, Krutzik teaches the device detects fluorescence, but is silent regarding a fluorescence filter. However, Sandstrom teaches the device further comprising an emissions filter and detector (i.e. collection optics Column 34, lines 47-65).

Regarding Claim 8, Krutzik teaches the device wherein the biodisc is attached to the cartridge using an adhesive (#118, Column 7, lines 21-24).

Regarding Claim 9, Krutzik teaches the device wherein the cartridge is a disc in which depressed portions are formed and the biodisc is installed in depressed portions (Fig. 15) wherein the biochip includes an adhesive (#118, Column 7, lines 21-24). Krutzik further teaches the cartridge wherein the adhesive member provides a fluidic circuit (Column 7, lines 36-39), but does not specifically teach that the biochip cannot be separated when the disc is rotated. However, sealed cartridges providing controlled assay environments were well known as taught by Sandstrom (Column 32, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of Krutzik to seal the cartridge while in use as taught by Sandstrom. One of ordinary skill in the art would have been motivated to do so for the well known benefits of controlled assay environments as desired in the art (Sandstrom, Column 32, lines 40-47).

Regarding Claim 10, Krutzik teaches the device wherein the disc is formed by spotting biocells within a groove (Column 19, lines 12-31 and Column 25, lines 42-47).

Regarding Claim 11, Krutzik teaches the device wherein the reflective film is selectively reflect allowing some light to pass and some light to be reflected (Column 15, lines 22-29, Fig. 20).

Regarding Claim 15, Sandstrom teaches the device further comprising a communication device for transmitting analysis and signal information to a readout device (Column 4, lines 53-67).

Regarding Claim 16, Krutzik teaches the device further comprising an optical recording unit (analyzer #168) for recording signals in response to trigger mechanism (#126/160) and output unit for producing analysis information (Column 3, lines 25-67).

Regarding Claim 17, Krutzik teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit (via trigger mechanism) using a single light source while controlling focusing and tracking (Column 13, lines 21-52 and Column s 14-15).

Regarding Claim 18, Krutzik teaches the device wherein the biodisc is attached to the cartridge using an adhesive (#118, Column 7, lines 21-24).

Regarding Claim 19, Krutzik teaches the device wherein the cartridge is a disc in which depressed portions are formed and the biodisc is installed in depressed portions (Fig. 15) wherein the biochip includes an adhesive (#118, Column 7, lines 21-24). Krutzik further teaches the cartridge wherein the adhesive member provides a fluidic circuit (Column 7, lines 36-39), but does not specifically teach that the biochip cannot be separated when the disc is rotated. However, sealed cartridges providing controlled assay environments were well known as taught by Sandstrom (Column 32, lines 40-47).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of Krutzik to seal the cartridge while in use as taught by Sandstrom. One of ordinary skill in the art would have been motivated to do so for the well known benefits of controlled assay environments as desired in the art (Sandstrom, Column 32, lines 40-47).

Regarding Claim 20, Krutzik teaches the device wherein the disc is formed by spotting biocells within a groove (Column 19, lines 12-31 and Column 25, lines 42-47).

Regarding Claim 21, Krutzik teaches the device wherein the reflective film is selectively reflect allowing some light to pass and some light to be reflected (Column 15, lines 22-29, Fig. 20).

Regarding Claim 25, Sandstrom teaches the device further comprising a communication device for transmitting analysis and signal information to a readout device (Column 4, lines 53-67).

7. Claims 12-14 and 22-24 are rejected under 35 U.S.C. 103(a) as obvious over Krutzik (U.S. Patent No. 7,141,416, filed 12 July 2002) in view of Sandstrom (U.S. Patent No. 6,545,758, issued 8 April 2003) as applied to Claims 1 and 15 above and further in view of Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 12-14, 22-24, Krutzik and Sandstrom teach the elements of Claims 1 and 15 as discussed above. Krutzik further teaches the device wherein a pin-spotter is used for patterning (Column 25, line 45) and Sandstrom also teaches a

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pin-spotter used for patterning (Column 23, lines 5764). The references do not teach a servo device for rotating the substrate at a predetermined speed while spotting and a controlled unit for controlling the servo device. However, servo devices providing controlled rotation while spotting a pattern onto the substrate was known in the art as taught by Wang.

Wang teaches a biochip readout device similar to that of Krutzik, the device comprising a rotatable biochip cartridge (#74) having a biochip installed on the disc (e.g. segment #70, Fig. 5, Column 14, lines 35-44). Wang further teaches a light reception means for receiving beam from the disc (i.e. focusing, tracking & header detector #134/136) having a light source scanning the disc (#102, Column 11, lines 40-67), a focusing/tracking control using the light reception means (Column 15, lines 28-45), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 15, lines 32-36), an optical pick-up device for analyzing the biosignals from the biochip (#124, Column 15, lines 45-58, Fig. 7) and a system and output controlling unit for monitoring analysis information, processing the signal (Column 17, lines 13-55).

Wang further teaches the device comprising a patterning device (printer) comprising a servo device for rotating the disc (raster scanner) and a printer for patterning the biocell on the substrate and a controller (servooptics) for controlling the entire system for rotation and printing (Column 12, lines 33-43 and Column 17, lines 24-47).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the controlled servo device of Wang to the device

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of Krutzik to thereby provide for patterned spotting using controlled rotation at constant speed to provide desired pattern on the substrate as taught by Wang (Column 12, lines 33-43). Wang teaches that using the same elements to align the biodisc for printing and detecting the array precisely and rapidly aligns the biochip (Column 12, lines 33-43). Therefore, one of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of rapid positioning as taught by Wang (Column 12, lines 33-43).

Prior Art

8. In the interest of compact prosecution, Applicant is advised of additional prior art. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Yamatus (U.S. Patent Application Publication No. 2005/0048595) teaches a biodisc device comprising disc drive, light reception means, focusing/tracking units and control units.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

/BJ Forman/
Primary Examiner, Art Unit 1634